510k Summary K122217

DEC 19 2012

Date:	12/13/2012
Subject:	510(k) Summary of Safety and Effectiveness Information for the NeuWave Medical Certus 140 2.45 GHz Ablation System and Accessories
Company:	NeuWave Medical, Inc. 3529 Anderson Street Madison, WI 53704
FDA Establishment#	3008769756
Contact:	Dan Kosednar, Director of Regulatory Affairs and Quality Assurance P – 608-512-1592 F – 608-512-1509
Proprietary:	Certus 140 2.45 GHz Ablation System and Accessories
Common:	System, Ablation, Microwave and Accessories
Classification:	General and Plastic Surgery, 73 NEY, 21 CFR 878.4440

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

Predicate Devices

The Certus 140 2.45 GHz Ablation System and Accessories is substantially equivalent to the following currently marketed device:

- Certus 140 2.45 GHz Ablation System and Accessories – Class II – 21CFG878.4400 which has been the subject of a cleared 510(k) with the FDA log number K100744 and K113237.

Indications For Use

The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.

The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures.

The system is designed for facility use and should only be used under the orders of a clinician.

Device Description

The system has a single 2.45 GHz signal source generator and three (3) independent power amplifiers, each capable of producing up to 140W each. One, easy to use, touch-screen user interface controls the system. Up to 3 microwave ablation probes can be connected to and powered by the system at one time. An intermediate junction box or Power Distribution Module (PDM) reduces system set up complexity.

Probes are provided sterile and are intended for single patient use only. Ablation probes are comprised of a sharp trocar on the end of a cannula, a probe handle, a 1.4 meter cable and a connector assembly.

Models Certus^{LN}, Certus^{LK}, and Certus^{PR} have 17 gauge cannula and are available in 15 cm and 20 cm lengths.

Model Certus^{SR}, has a 13 gauge cannula and is available in a 25 cm length only.

Each probe contains three (3) temperature measurement sensors that help monitor performance and ensure patient and operator safety.

Additionally, different ablation probes have been designed to optimize the energy transfer efficiency from the probe into different types of tissue based on known electrical properties of each tissue.

Certus^{LK} probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in liver and kidney tissue. Certus^{LN} probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in lung tissue.

The antenna of the Certus^{PR} probe is designed to limit the length of the ablation for instances when a shorter ablation zone is desired. Certus^{PR} Probes were developed to provide physicians with an additional ablation probe designed specifically for ablating smaller lesions. The Certus^{PR} probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation. Certus^{PR} probes will enable physicians to ablate smaller lesions while limiting necrosis of adjacent tissue when compared to other Certus probes.

A CO_2 based cooling system ensures the non-active portion of the probe does not exceed temperature requirements. Additionally, the CO_2 enables the Tissu-Loc function, which can be used to adhere or stick the probe in place prior to starting ablation therapy. This function is similar in use to the stick function available on cryogenic ablation systems.

The system uses two (2) E-sized CO_2 cylinders. When a tank in use empties, the system will automatically switch to using the other tank and notify the user to replace the empty tank.

Modifications

This 510(k) was submitted to update the Certus 140 system with:

- new software to improve the ease of use during open surgical procedures, specifically surgical coagulation and Planar Coagulation applications. The new software interface has distinct "Ablation Mode" and "Surgical Mode".
- A footswitch is now available to control probe delivery in Surgical Mode
- A new Dual Probe Clip accessory was developed to hold two 17 gauge Certus probes.
- In Surgical Mode, the maximum power setting for Certus^{PR} probes has changed from 65W to 95W if one or two probes are active
- The generator frequency output is 2.450GHz +/- .025GHz, nominal

Performance Data

The Certus 140 2.45 GHz Ablation System and Accessories has been designed to comply with the applicable portions of various International Standards, including:

- UL 60601-1:2003
- IEC 60601-1:1988 Plus Amendments
- IEC 60601-2-2:2006
- IEC 60601-2-6:1984
- IEC 60601-1-2:2007
- EN ISO 11607-1:2009
- ISO 10993-1: 2009

The Certus 140 2.45 GHz Ablation System and Accessories and the predicate devices are substantially equivalent in design concepts, technologies and materials. The Certus 140 Ablation 2.45 GHz System and Accessories has been verified through rigorous testing that, in part, supports the compliance of Certus 140 2.45 GHz Ablation System and Accessories to the standards listed above.

Ex-vivo studies were conducted to compare the performance of the Certus 140 2.45 GHz Ablation System and Accessories to a predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NeuWave Medical, Incorporated
% Mr. Dan Kosednar
Director, Regulatory Affairs and Quality Assurance
3529 Anderson Street
Madison, Wisconsin 53704

December 19, 2012

Re: K122217
Trade/Device Name: Certus 140 Microwave Ablation System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: December 13, 2012
Received: December 14, 2012

Dear Mr. Kosednar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Certus 140 Microwave Ablation System and Accessories

Indications For Use:

The NeuWave Medical Certus 140™ 2.45 GHz Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.

The Certus 140™ 2.45 GHz Ablation System is not indicated for use in cardiac procedures.

The system is designed for facility use and should only be used under the orders of a clinician.

Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D. Rumm -S

Concurrence for the Division of Surgical Devices/ODE/CDRH

K122217